Division of Digestive Diseases and Nutrition

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September 2000 Council

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Division of Digestive Diseases and Nutrition

Initiatives, Expansions or Extensions

3001 STUDY OF HEALTH OUTCOMES OF WEIGHT-LOSS ANCILLARY STUDIES (RFA DK-00-017)

FY 2001 Action

The Study of Health Outcomes of Weight-Loss (SHOW) clinical trial will investigate the health effects of interventions designed to produce long-term weight loss in overweight and obese individuals with type 2 diabetes. A Request for Applications (RFA) for "Ancillary Studies in Conjunction with SHOW" was released on August 2, 2000 for funding in FY 2001. This RFA solicits R01 grants to take advantage of the availability of such a well-described and diverse population of obese individuals with type 2 diabetes undergoing long-term weight loss interventions. The RFA is cosponsored by the National Heart, Lung and Blood Institute, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Nursing Research, and National Institute of Dental and Craniofacial Research. Applicants are encouraged to propose studies that investigate health disparities in subpopulations defined by variables such as ethnicity/race, gender, or socioeconomic status.

Background

Numerous studies have demonstrated the beneficial impact of short-term weight loss on risk factors such as dyslipidemia, hyperinsulinemia, hypertension, and elevated plasma glucose. Based on long-term epidemiological evidence of the health hazards of overweight and obesity and on shorter term clinical trial evidence, public health policy recommends weight loss for obese individuals (body mass index [BMI] 30 or above) or overweight individuals (BMI 25.0 to 29.9) with one or more additional comorbidities.

Currently in the U.S., 40 percent of women and 25 percent of men are attempting to lose weight, using a variety of means. Despite this fact, few studies have examined the health effects of intentional weight loss over a period greater than one year and very few beyond four years. Moreover, several major observational studies show a significant association between weight loss and mortality that persists even after attempts to correct for confounding factors (e.g., smoking or pre-existing illness). However, most of these observational studies are unable to distinguish between voluntary and involuntary weight loss.

The SHOW trial is a multicenter clinical trial to investigate the benefits and risks of interventions designed to sustain weight loss over the long term. The SHOW trial is currently in the design phase, and is expected to begin enrollment in spring of 2001. The study will enroll 6,000 overweight patients with type 2 diabetes over a period of three years, randomizing them to either standard medical (community) care or intensive life-style modification that may include pharmacological therapy. Long-term health benefits will be monitored; with the primary endpoint being combined cardiovascular deaths (including fatal myocardial infarction and stroke), non-fatal myocardial infarction, and non-fatal stroke.

Research Goals and Scope

The purpose of this initiative is to solicit applications for a range of basic, clinical, and behavioral ancillary research studies that are consistent with the aims of SHOW. These

ancillary studies can enhance investigation of the response of the various participants' characteristics to weight loss interventions, the impact of weight loss interventions on obesity-related comorbid conditions, the relationship of genetic factors to these responses, and the psychosocial correlates or determinants of behavior change. In addition, the SHOW cohort may offer the opportunity for ancillary studies to examine the incidence or progression of obesity-related pathological conditions in populations in which additional study is needed, to identify biomarkers for disease risk, and to investigate relatively rare or understudied obesity-related conditions in this large sample.

Examples of research topics considered responsive to this RFA include, but are not limited to:

A. Genetic Studies, such as: mutation and polymorphism detection and genotype/phenotype association studies.

B. Metabolic/Physiological studies, such as: substrate utilization as a function of treatment/weight loss; lipid metabolism and kinetics; insulin action and glucose disposal; modulation of inflammatory markers/mediators; left ventricular mass or function; and effects of hormonal status on response to intervention.

C. Natural History of Comorbid Conditions or Impact of Interventions on Conditions such as: sleep apnea; diabetic eye disease; urologic and renal disease; non-alcoholic steatohepatitis; osteoporosis/bone density; osteoarthritis; periodontal disease; and subclinical cardiovascular disease measures.

D. Psychosocial, Behavioral, and Economic Correlates or Predictors in research areas such as: health and/or physiological outcomes; long term weight maintenance; eating behaviors; psychopathology; diet and physical activity; and changes and adherence to medications.

E. Measures and Methodology Studies such as: body composition measures other than total fat and fat free mass; objective measures of diet or physical activity complementary to those proposed for SHOW; measures of subclinical disease; and measures of medication adherence.

3003 CLINICAL RESEARCH NETWORK TO STUDY NON-ALOCOHOLIC STEATOHEPATITIS (NASH)

FY 2001 Action

A Request for Applications (RFA) will be released in November 2000 for an interlocking set of cooperative agreements to design and implement a database and clinical research network to study the etiology, natural history, course, complications, contributing factors and therapy of non-alcoholic steatohepatitis (NASH). Cooperative agreement grants will be requested for four to six clinical centers and a data coordinating center to establish a large clinical cohort of patients with NASH to be followed in a natural history study and undergo clinical investigation as to the etiology and contributing factors for development and worsening of this disease. The network will provide a mechanism by which to conduct pilot studies followed by full-scale clinical trials of promising therapies of this disease.

Background

NASH is a common liver disease of unclear etiology that is characterized by fat accumulation in the liver (steatosis) as well as inflammation and necrosis (hepatitis). Histologically, the disease resembles alcoholic liver disease, but it occurs in patients who drink sparingly or not at all. The disease is usually asymptomatic and is often discovered only when a person is found to have elevations in serum aminotransferase levels. Nevertheless, the disease can progress to cirrhosis and end-stage liver disease and may account for 10 to 15 percent of liver transplants done in the U.S. NASH typically occurs in middle-aged persons who are overweight and diabetic. However, it can also be found in normal weight individuals, in non-diabetics, in children, and in the elderly. A common underlying factor appears to be insulin resistance, but the mechanism of liver injury remains unclear. Other contributing factors appear to be dyslipidemia, oxidative stress, excess iron accumulation, and proinflammatory cytokines. While the disease is common, its course and natural history have not been defined. At present there is no specific therapy for NASH. In small uncontrolled studies, weight loss, anti-oxidants, hydrophilic bile acids and anti-diabetic therapies have been associated with minor improvements in blood test results, but no studies have documented improvement in liver histology or natural history and outcome of disease.

Research Goals and Scope

The RFA will be for interlocking cooperative agreements for four to six clinical centers and a data coordinating center. The investigators will develop a detailed clinical protocol for enrollment of a large cohort of patients into a prospective database. The investigators will develop clinical and histological definitions and criteria for diagnosis and stages of the disease. The database will be used for epidemiological studies of risk factors as well as a source of patients for detailed clinical investigation. The Clinical Research Network will also establish pilot studies of promising therapeutic approaches and when appropriate, full scale clinical trials of therapies for NASH.

3004 CHRONIC HEPATITIS C IN AFRICAN AMERICANS: STUDY OF RESISTANCE TO ANTIVIRAL THERAPY IN CHRONIC HEPATITIS C (VIRAHEP-C) (RFA DK-00-007)

FY 2001 Action

A Request for Applications (RFA) will be released in September 2000 for an interlocking set of cooperative agreements to design and implement a study of the frequency, pattern, nature and cause of antiviral resistance in chronic hepatitis C, focusing upon a cohort of African Americans among whom such resistance is common.

Background

The hepatitis C virus (HCV) is probably the major cause of cirrhosis and end-stage liver disease in the U.S.--accounting for 8,000 to10,000 deaths per year and at least 30 percent of all liver transplants done in adults in the U.S. Hepatitis C is two- to three-fold more common among African Americans than non-Hispanic Caucasians. The current optimal therapy of chronic hepatitis C is a combination of alpha interferon and ribavirin given for 24 to 48 weeks. Retrospective analyses of studies of antiviral therapy have shown that response rates are two- to three-fold less among African American patients than among non-Hispanic Caucasians with hepatitis C. The reasons for this difference are not clear, but may be due to viral strain or genotype, immunological factors, or genetic differences in interferon signaling and response pathways. Unfortunately, studies of antiviral therapy have included too few African American patients to provide reliable estimates of the response rate to current therapies or to analyze factors responsible for a lack of effect of therapy. Better information is needed, to help improve response rates among African Americans as well as to provide valid clinical recommendations for treatment.

Research Goals and Scope

The RFA for this cooperative agreement will call for applications for eight clinical centers, four ancillary research studies, and a data coordinating center. The investigators will develop a detailed clinical protocol and strategies for analysis of the mechanism of antiviral effect and resistance to alpha interferon in chronic hepatitis C. During the study itself, each clinical center will enroll and treat 50 patients (25 African Americans and 25 non-Hispanic Caucasians) with chronic hepatitis C using the optimal regimen of therapy. Samples will be collected for the ancillary investigations of virological, cell signaling, immunological and genetic factors that may play a role in antiviral resistance in hepatitis C. The research goals will be to address five research questions: (1) Are there differences in sustained virological response rates among African Americans and non-Hispanic Caucasians? (2) What factors predict a response in both groups and are they different? (3) Do the early viral kinetics predict ultimate outcome of therapy? (4) Can a simple, clinically useful algorithm be developed to guide clinical decision-making in therapy for both African American and non-Hispanic Caucasians? (5) What are the virological, immunological, genetic and pharmacokinetic causes of viral resistance to combination therapy in chronic hepatitis C?

3005 PATHOGENESIS OF NON-ALCOHOLIC STEATOHEPATITIS

FY 2001 Action

This initiative will consist of a program announcement (PA) aimed at expanding research on the pathogenesis of nonalcoholic steatohepatitis (NASH). The major focus of the PA will be to elucidate the cellular, hormonal and genetic mechanism(s) by which injury occurs in this disease. In addition to R01 applications, this initiative will encourage development of new research tools through the exploratory/developmental grant mechanism (R21).

Background

In western countries, the most common cause of liver enzyme abnormalities among adults is a poorly defined condition, now known as non-alcoholic steatohepatitis (NASH). The disease typically occurs in middle aged, overweight women with diabetes or hyperlipidemia. In many instances, the condition is benign. But cases of progressive disease that eventuate in cirrhosis and end-stage liver disease have been described, and as many as 10 to 15 percent of liver transplants done in the U.S. yearly may be due to NASH. The difficulty is that the disease has not been well defined. It is marked by significant hepatic steatosis as well as necrosis. The character of the injury resembles alcoholic liver disease and patients usually have "centrolobular" (zone 3) fibrosis and scattered Mallory bodies, which are also typical of alcoholic liver disease. NASH occurs most commonly in overweight individuals and improvements in liver tests have often been reported with weight loss. The disease is also associated with diabetes and insulin resistance. Indeed, the most severe examples of NASH are found in young persons with severe, genetic insulin resistance states. However, the disease in mild forms is common in the general population and may be found in 3 to 5 percent of otherwise normal American adults. Little is known about the pathogenesis of NASH, but underlying themes include insulin resistance, dyslipidemia, and abnormal cytokines.

Research Goals and Scope

Studies are needed on the pathogenesis and mechanisms of liver cell injury in NASH, mechanism(s) of liver fibrosis and liver cell necrosis--particularly through the generation of new animal and cell culture models. Studies are needed to investigate mechanisms of augmented liver matrix formation and hepatic fibrosis formation induced by steatosis. Another goal is the development of readily available cell culture systems as well as small animal models.

3006 MILK THISTLE IN THE TREATMENT OF HEPATIC DISEASES (RFA AT-00-003)

FY 2001 Action

With the National Center for Complementary and Alternative Medicine (NCCAM), the Division of Digestive Diseases and Nutrition will cosponsor an RFA for development of an appropriate standardized preparation of silymarin, the active ingredient of milk thistle, a botanical herbal medication commonly used for liver disease. This RFA will request the preparation of a reliable constant supply of silymarin for clinical research, including human trials, as well as basic research. This RFA provides a flexible system within the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs to accommodate the extensive needs and complex development process.

Background

The use of silymarin in chronic liver disease was recently reviewed in the NIDDK/NCCAM symposium: "Complementary and Alternative Medicine in Chronic Liver Disease." The hepatoprotective properties of silybinin against a variety of hepatotoxins are established by experimental data. In contrast, the clinical benefits of silymarin therapy have yet to be established. Conflicting data has emerged from randomized controlled studies in the treatment of chronic liver disease. No randomized trials have yet been performed in patients with chronic hepatitis C, although small pilot studies have shown a lowering of serum enzymes without accompanying loss of HCV RNA levels. Silymarin, which is found in the entire milk thistle plant, is concentrated in the fruit and seeds. Extracts of milk thistle contain anti-oxidant flavenoids--silybinin, silydianan and silichristin--which are believed to be the active ingredients. Silybinin constitutes 60 to 90 percent of silymarin and is the component with the greatest degree of biological activity. Milk thistle extracts are usually standardized to contain 70 to 80 percent silybinin. The first challenge will be to identify a pure and standardized product and then to consider which form of liver disease is likely to benefit from rigorously developed and conducted treatment trials.

Research Goals and Scope

To support projects that could lead to development of appropriate standardization and provision of a reliable, constant supply of milk thistle. The RFA will also call for biological assays to measure silybinin levels, so that pharmacological studies can be done and appropriate regimens and dosages for human trials, as well as basic research be developed.

3007 DOUBLY-LABELLED WATER RESOURCE FOR RESEARCH

FY 2001 Action

Facilitated by the NIH Division of Nutrition Research Coordination, the Division of Digestive Diseases and Nutrition in collaboration with other ICs and federal agencies (USDA and DoD) will co-sponsor a Request for Proposals (RFP) to purchase a supply of oxygen-18. The purpose of this contract initiative is to provide for an important resource for investigators involved in clinical research related to energy expenditure, body composition and obesity. The stable isotope of oxygen, ^{18}O, is used as a component of the doubly-labelled water methodology for the assessment of energy expenditure in the free-living individual.

Background

Oxygen-18 is a stable isotope that is used as a tracer for several biomedical applications. The two primary applications are the study of energy expenditure and organ specific utilization of glucose. The former uses oxygen-18, along with deuterium to measure carbon dioxide production of free-living animals and humans. Total energy expenditure is calculated from carbon dioxide production using the standard equations of indirect calorimetry. The latter uses ^{18}O as a precursor for the production of ^{18}F, a radionuclide that is incorporated into glucose homologs and injected into the circulating blood. When an organ (usually brain) takes up the glucose homologs, the organ can be imaged using positron emission tomography (PET). Both of these techniques have become major research tools and, in the case of PET, diagnostic tools during the last decade. This growth in the use of these tools has increased the worldwide demand for ^{18}O in the form of water. In 1998, suppliers could not meet this demand and many investigators and clinicians have encountered significant delivery delays. Some suppliers are quoting delivery delays of a year. These delays have disrupted on-going research and delayed the start of new projects. The shortage has resulted in a price increase of nearly 50 percent in ^{18}O water. There are four commercial ^{18}O producers in the world--Cambridge Isotope Labs (U.S.), Isonics (Russia), Isotec (U.S.) and ROTEM (Israel). While supply is estimated to improve, estimated production capacity to date has not been sufficient to eliminate the backlogged demand.

Research Goals and Scope

The objectives of this initiative are technical rather than scientific and involve deliverables that are to be made available to investigators to facilitate the pursuit of grant-supported scientific investigations. This contract initiative will attempt to provide a sufficient supply of ^{18}O to allow investigators assurance to be able to complete ongoing investigations. It should also allow new investigations to be proposed utilizing this state-of-the-art technology without jeopardizing judging the scientific merit during the review due to the known lack of the isotope.

3008 NATIONWIDE STUDY OF ACUTE HEPATITIS C (NATA-HEP C)

FY 2001 Action

The Division of Digestive Diseases and Nutrition, with the Centers for Disease Control and Prevention (CDC), the Veterans Administration, the Department of Defense, and the National Institute of Allergy and Infectious Diseases, will cosponsor a Request for Proposals (RFP) to develop a nationwide study of acute hepatitis C. The study will analyze the frequency, course and outcome of cases of acute hepatitis C following accidental occupational exposure to hepatitis C infected blood or secretions. Persons who develop acute hepatitis C virus (HCV) infection will be offered enrollment in a randomized trial of immediate versus delayed combination therapy using interferon and ribavirin.

Background

Hepatitis C is the most common cause of chronic hepatitis in the Western world and can lead to cirrhosis, end-stage liver disease and hepatocellular carcinoma. An important characteristic of hepatitis C is its propensity to cause chronic hepatitis. In prospective studies, 75 to 85 percent of adults with acute HCV infection develop chronic infection that is usually life-long. At present, a major cause of acute hepatitis C is accidental exposure in the work-place, accounting for cases of this disease in nurses, physicians, phlebotomists, and other healthcare workers. Approximately 5 to 10 percent of persons with an accidental needle stick injury from a patient with HCV infection acquire hepatitis C and the majority develop chronic liver disease. At present, therapy of hepatitis C is recommended for patients with chronic infection and raised serum aminotransferase levels. An obvious possibility is that early therapy during acute hepatitis C may be more efficacious than therapy once the disease is established. However, there is little information on the efficacy and relative safety of this approach as compared to waiting until the disease is chronic. It is possible that early therapy with interferon and ribavirin (the current recommended regimen for chronic hepatitis C) might be more effective in eradicating infection than therapy of chronic hepatitis C. On the other hand, therapy is expensive and has serious potential side effects, and another approach is to only treat patients who develop chronic hepatitis and clear indications for therapy. Without a prospective randomized trial comparing early versus delayed therapy, recommendations for management will be based upon opinion rather than scientific evidence.

Research Goals and Scope

In collaboration with the CDC, the Division of Digestive Diseases and Nutrition is preparing an RFP for a nationwide study of acute hepatitis C after accidental needle stick exposure. This study will require at least 30 clinical centers spread throughout the U.S. Each clinical center will be expected to evaluate between 30 and 100 needle stick accidents yearly and acquire two to five patients with acute hepatitis C who can be randomized to receive either immediate therapy with interferon and ribavirin or delayed treatment after six months.

3009 GASTROINTESTINAL MOTILITY AND FUNCTIONAL BOWEL SYNDROME

FY 2001 Action

The Division of Digestive Diseases and Nutrition will prepare a Program Announcement (PA) requesting applications to study gastrointestinal motility, motility disorders and functional bowel syndrome. This PA is in follow-up to a Request for Applications (RFA) published in FY 1999 entitled "Integrative Approaches to Motility of GI Tract." A special emphasis of this PA will be on pediatric motility disorders. Both full scale (RO1s) as well as innovative-development grants (R21s) will be solicited.

Background

Motility disorders of the gastrointestinal tract present a major health problem for the U.S. population with complaints such as frequent heartburn to constipation. It has been estimated that over 5 million Americans report having irritable bowel syndrome: fecal incontinence affects approximately 7 percent of the U.S. population especially the elderly. Other disorders such as constipation affect over 4 percent of the population and another 14 percent of the population report reflux symptoms on a weekly basis. In the U.S., it has been estimated that 2.5 out of 1,000 live births will have a motility disorder called pyloric stenosis. Also, another motility disorder, Hirschsprung's disease, which results from an absence of nerves in the anorectal area, occurs in 1 in 5,000 live births. In addition, there is a growing awareness of the GI motility disorder in children known as cyclical vomiting syndrome and other bowel disturbances as reflected in the number of support groups for these disorders.

Recently the Division has increased its support of motility grants through an RFA DK99-004, entitled "Integrative Approaches to the Study of Motility GI Tract." The Division was able to support 17 grants with a total of $2.1 million in FY 1999 and FY 2000 and subsequently three more motility grants have been funded from FY 2000 allocations since the issuance of that RFA.

Research Goals and Scope

This Program Announcement, with participation of the National Institute of Child Health and Human Development (NICHD), would serve as a mechanism to encourage highly innovative research studies of the enteric nervous system, the role of ion channel and interstitial cells of Cajal on motility, and the interaction of the neuromuscular apparatus of the gut and the immune system. Additional research evaluating electrophysiological studies of the smooth muscle of gut, as well as biologic markers for visceral hypersensitivity and brain imaging studies, would be encouraged. In addition, this initiative would encourage studies of pediatric motility disorders, the development of clinical trials to evaluate pharmacological and non-pharmacological approaches to the treatment of functional bowel disorders, cyclical vomiting syndrome, constipation, and fecal incontinence.

3012 CLINICAL TRIALS IN DIGESTIVE AND NUTRITIONAL DISEASES

FY 2001 Action

The Division of Digestive Diseases and Nutrition will continue to solicit plans for important clinical trials in digestive diseases and nutritional disorders using the small grant (R03) mechanism. In FY2001, the Division will reissue a Program Announcement (PA) soliciting applications for small, planning grants to develop full-scale multicenter trials of therapy in digestive and nutritional diseases.

Background

PA-98-071, "Small Grants in Digestive and Nutritional Disorders," has been published which supercedes PA-95-078, “Small Grants for Clinical Trials.” The current PA adds several focus areas: epidemiology of digestive and nutritional disorders, endoscopic research, hepatitis C, non-alcoholic steatohepatitis (NASH) and celiac disease. This PA is the source of approximately 20 applications for planning grants each year and has resulted in a clinical trials program that currently funds 34 R03s in areas such as infant diarrhea, pediatric liver disease, helicobacter pylori infection, inflammatory bowel disease, primary biliary cirrhosis and sclerosing cholangitis, acute liver failure, pancreatitis, common bile duct stone disease, and obesity. The R03 program has led to development of full scale clinical trials including studies of methotrexate therapy of primary biliary cirrhosis, use of TIPS in ascites and for intractable variceal hemorrhage, use of acetylcysteamine in acute liver failure and dietary therapies of obesity. This PA will need renewal in FY2001. The major changes in the announcement will be to increase the size and duration of the awards and to refocus upon specific diseases that are particularly deserving of further clinical investigation including obesity, inflammatory bowel disease, functional bowel disease, motility disorders in children, ulcer disease induced by non-steroidal anti-inflammatory agents, celiac disease, biliary atresia, drug-induced liver disease, chronic hepatitis B and C and acute pancreatitis.

Research Goals and Scope

The PA will solicit planning grants for development of clinical trials in important digestive and nutritional diseases. The major purpose is to provide means by which investigators can generate appropriate clinical trial design and preliminary data to support an application for a full-scale clinical trial.

3014 EXPAND WEIGHT-CONTROL INFORMATION NETWORK'S SISTERS TOGETHER

FY 2001 Action

NIDDK's Weight-control Information Network (WIN) provides culturally appropriate, evidence-based information about obesity, physical activity, weight control, and adolescent and childhood obesity to people who are overweight and/or obese, the general public, health care providers, the media, and the Congress. In addition to creating and distributing materials, WIN developed the "Sisters Together: Move More, Eat Better" pilot program for African American women because data from the Third National Health and Nutrition Examination Survey (NHANES III) indicate that they have the highest rates of obesity and overweight among all racial and ethnic groups in the U.S. WIN plans to implement a nation-wide, media-based "Sisters Together: Move More, Eat Better" program for African American women ages 18 and over. WIN will also develop partnerships with agencies and organizations that encourage and promote healthy lifestyle behaviors for many audiences, particularly African American audiences. The "Sisters Together: Move More, Eat Better" program is a part of NIDDK's Strategic Plan on Minority Health Disparities.

Strategies being considered are publicizing the availability of current "Sisters Together" materials and plans to expand outreach to churches, community organizations, state and local health departments, black media outlets, and black organizations such as the National Black Women's Health Project and the National Caucus and Center on Black Aged.

As WIN plans to expand the "Sisters Together: Move More, Eat Better" program to a national audience, it will also sponsor local activities for African American women living in the Washington metropolitan area. For the "Sisters Together: Move More, Eat Better" messages and activities to resonate with African American women nationally, WIN will nurture and facilitate partnerships with national, state, and local groups and individuals. WIN is currently developing relationships with nontraditional partners such as hair and nail salons.

Background

The "Sisters Together: Move More, Eat Better" program was piloted from 1995 to1998 in the three Boston-based, predominantly black communities of Dorchester, Mattapan, and Roxbury. The program activities consisted of community outreach activities such as walking groups and cooking demonstrations, distribution of materials promoting healthy eating and regular exercise, and media outreach.

To increase awareness among African American women about the health benefits of regular exercise and healthy eating, WIN, through its "Sisters Together: Move More, Eat Better" program, created a planning guide that details the steps used to develop the Boston-based "Sisters Together" program. The guide helps individuals and organizations plan, promote, implement, and evaluate health awareness programs designed for African

American women. The guide is distributed to churches, community organizations, and black media outlets.

Research Goals and Scope

The purpose of the "Sisters Together: Move More, Eat Better" program is to raise awareness about how moving more and eating better improve health, reduce risks for certain diseases, and, ultimately, enhance quality of life. A national "Sisters Together" program will also aim to develop and disseminate new, culturally relevant messages based on recent scientific findings about lifestyle interventions, obesity, and physical activity. Partnerships with new organizations and individuals will also be pursued during the expansion of the "Sisters Together" program.

3015 HEALTH AWARENESS CAMPAIGN ON HEPATITIS C FOR AFRICAN AMERICANS AND HISPANIC/LATINO AMERICANS

FY 2001 Action

The NIDDK publishes a series of easy-to-read booklets on hepatitis through its National Digestive Diseases Information Clearinghouse (NDDIC). The series is also available in Spanish. The NIDDK, in collaboration with other organizations, plans to establish a coordinated information program about hepatitis C in African Americans and Hispanic/Latino Americans. The NIDDK will work with public and private partners representing African American and Hispanic/Latino Americans to identify additional needs of patients, families, and physicians and will develop messages and materials to address these needs. The NIDDK will also publicize clinical trial recruitment and the results of research. This program is part of NIDDK's Strategic Plan on Minority Health Disparities.

As a first step towards raising awareness, the NDDIC will begin drafting a communications strategy plan. The objectives for this plan are: (1) to raise awareness that hepatitis C can be screened and identified effectively in African Americans and Hispanic/Latino Americans; (2) to clarify misconceptions about hepatitis C, such as possible transmission modes; and (3) to increase communication about hepatitis C between patients and health professionals in African American and Hispanic/Latino American communities.

Background

Data from the Agency for Healthcare Research and Quality's (AHRQ) Medical Expenditure Panel Survey reveal that about 30 percent of Hispanic and 20 percent of African Americans lack a usual source of health care compared with less than 16 percent of Caucasians. African Americans and Hispanic/Latino Americans are far more likely to rely on hospitals or clinics for their usual source of care than are Caucasian Americans (16 and 13 percent, respectively, versus 8 percent). These statistics indicate that African Americans and Hispanic Americans are less likely to be appropriately screened and treated for hepatitis C. AHRQ suggests a need to focus on why these disparities exist, which disparities actually indicate poor-quality care, and how to develop strategies to address them.

Research Goals and Scope

NIDDK will need to (1) convene preliminary strategy sessions with the director of the Division of Digestive Diseases and Nutrition, Office of Communications and Public Liaison staff, and clearinghouse staff; (2) seek partnerships with related governmental agencies (e.g., Centers for Disease Control and Prevention) and professional and voluntary organizations; and (3) implement strategies.

DIVISION OF DIGESTIVE DISEASES AND NUTRITION
Conferences and Workshops

New Directions in Drug Induced Liver Injury: Mechanisms and Test Systems
October 17-18, 2000

This workshop will focus on mechanisms of hepatotoxicity with clinical-pathological correlations. This meeting is meant to bring forth ideas for future research and particularly how this difficult area can achieve research funding commensurate with its growing importance. Possibilities include a Request for Applications (RFA) for basic research on specific hepatotoxins or pathways of drug-induced liver injury or development of multidisciplinary grants in this area, that would include a database on patients with hepatotoxicity and specific research projects that are based upon serum, tissue, cells and DNA from well-characterized cases from the database.

The meeting is aimed at helping to define needs and directions for future research in hepatotoxicity. Its goals are: (1) to provide an opportunity for cross-fertilization with the liver scientific community and to enhance our knowledge of the epidemiology of hepatotoxicity through interagency collaborations with the Food and Drug Administration and the Centers for Disease Control and Prevention; (2) to further the understanding of the mechanisms of drug- and complementary/alternative medicine-induced hepatotoxicity; (3) to develop experimental (*in vivo*, *in vitro*) models to assess potential hepatotoxins; (4) to promote further study of hepatotoxicity in the general population, women, minorities and high-risk (elderly and infants) populations, through the issuance of a Program Announcement; and (5) to develop preventive and educational measures.

Living Donor Liver Transplantation
December 4-5, 2000

This workshop will focus on the current status and recent advances made in the area of adult-to-adult living donor liver transplantation. This meeting is meant to bring forth ideas for future research and particularly how this difficult area can achieve research funding commensurate with its growing importance. Possibilities include a Request for Applications (RFA) for a cooperative agreement to establish a prospective database on living donors focusing upon the possible long-term consequences of right lobectomy in healthy adults. The database would also focus on informed consent and psychological consequences of living donor transplantation.

The meeting is aimed at helping to define needs and directions for future research in living donor liver transplantation. An important goal is the development of a research initiative to further knowledge about the consequences of living donor liver transplantation, both for the donor and the recipient. The organizers of the conference will write a summary, a major component of which will be to define the needs for future research.

Clinical Trials in Prevention of Obesity in High Risk Populations
Summer 2001

A two-day workshop will take place in the summer of 2001, to which all of the grantees from the trans-NIH Request for Applications (RFA) on Innovative Approaches to Prevention of Obesity (DK-99-010) will be invited. The focus of the meeting will be to share research progress among investigators conducting pilot studies of obesity prevention in high-risk populations. Investigators will also help to assess what strategies are worth further pursuit in full-scale or long term obesity prevention studies. A particular focus in all of these efforts will be on preventive strategies in minority populations.

This workshop aims to extend the impact of the trans-NIH RFA on "Innovative Approaches to the Prevention of Obesity." The Workshop will bring together investigators working on many different avenues of clinical research on obesity in high-risk populations to share their progress and to help guide development of a new initiative for full-scale clinical trials in obesity prevention.

Barrett's Esophagus and Adenocarcinoma of the Esophagus

The Division of Digestive Diseases and Nutrition (DDDN) and the National Cancer Institute (NCI) will develop a series of meetings to assess the level of funding and areas of supported research in the area of reflux esophagitis and Barrett's esophagus, a precancerous lesion for adenocarcinoma of the esophagus. These meetings will lead to a joint NIDDK-NCI initiative for workshops on specific areas and delineation of future needs in research.

The Barrett's esophagus working group, made up of NCI and DDDN scientists, will organize a series of scientific workshops to develop research strategies in addressing the rising incidence of adenocarcinoma of esophagus. These workshops are expected to lead to joint RFAs and initiatives in Barrett's esophagus to be developed for FY 2002 and 2003.